

doctor. If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.”

(2) “This product may cause temporary burning and irritation on being instilled into the eye.”

(3) “If solution changes color or becomes cloudy, do not use.”

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions”: Instill 1 or 2 drops in the affected eye(s) every 3 or 4 hours, or as directed by a doctor.

#### § 349.75 Labeling of ophthalmic vasoconstrictor drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug(s), if any, and identifies the product as a “redness reliever” or “vasoconstrictor (redness reliever)” (select one of the following: “eye” or “ophthalmic”) “(insert dosage form, e.g., drops).”

(b) *Indications*. The labeling of the product states, under the heading “Indications,” the following phrase: “Relieves redness of the eye due to minor eye irritations.”

(c) *Warnings*. In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading “Warnings” for products containing any ingredient identified in § 349.18:

(1) “If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours, discontinue use and consult a doctor.”

(2) “If you have glaucoma, do not use this product except under the advice and supervision of a doctor.”

(3) “Overuse of this product may produce increased redness of the eye.”

(4) “If solution changes color or becomes cloudy, do not use.”

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions”: Instill 1 to 2 drops in the affected eye(s) up to four times daily.

EFFECTIVE DATE NOTE: At 65 FR 38428, June 21, 2000, § 349.75 was amended by revising paragraph (c)(2) and by adding paragraph (c)(5), effective May 16, 2002. For the conven-

ience of the user the revised and added text is set forth as follows:

(c) \* \* \*

(2) “Ask a doctor before use if you have [in bold type] narrow angle glaucoma.”

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(5) “When using this product [in bold type] pupils may become enlarged temporarily.”

#### § 349.78 Labeling of eyewash drug products.

(a) *Statement of identity*. The labeling of the product identifies the product with one or more of the following terms: “eyewash,” “eye lotion,” or “eye irrigating solution.”

(b) *Indications*. The labeling of the product states, under the heading “Indications,” one of the following phrases:

(1) “For” (select one of the following: “flushing,” “irrigating,” “cleansing,” “washing,” or “bathing”) “the eye to remove” (select one or more of the following: “loose foreign material,” “air pollutants (smog or pollen),” or “chlorinated water”).

(2) “For” (select one of the following: “flushing,” “irrigating,” “cleansing,” “washing,” or “bathing”) “the eye to help relieve” (select one or more of the following: “irritation,” “discomfort,” “burning,” “stinging,” “smarting,” or “itching”) “by removing” (select one or more of the following: “loose foreign material,” “air pollutants (smog or pollen),” or “chlorinated water”).

(c) *Warnings*. In addition to the warnings in § 349.50, the labeling of the product contains the following warnings under the heading “Warnings” for all eyewash products:

(1) “If you experience eye pain, changes in vision, continued redness or irritation of the eye, or if the condition worsens or persists, consult a doctor.”

(2) “Obtain immediate medical treatment for all open wounds in or near the eyes.”

(3) “If solution changes color or becomes cloudy, do not use.”

(d) *Directions*. The labeling of the product contains the following information under the heading “Directions”:

(1) *For eyewash products intended for use with an eyecup*. Rinse cup with